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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,193	05/11/2001	Greta Van Den Berghe	6296.204-US	5893
23650	7590	03/18/2005	EXAMINER	
NOVO NORDISK, INC.			KAM, CHIH MIN	
PATENT DEPARTMENT			ART UNIT	
100 COLLEGE ROAD WEST			PAPER NUMBER	
PRINCETON, NJ 08540			1653	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/853,193

Applicant(s)

VAN DEN BERGHE, GRETA

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-14,22-29 and 32-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,7-14,47-61 and 74-85 is/are allowed.
- 6) ☒ Claim(s) 1,22-29,37-39,45,46,72 and 73 is/are rejected.
- 7) ☒ Claim(s) 32-36,40-44 and 62-71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/24/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed January 24, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1, 4, 7-14, 22-29 and 32-85 are pending.

Applicant's amendment and response filed January 24, 2005 are acknowledged, and applicants' response has been fully considered. Claims 1, 4, 7, 22 and 23 have been amended, claims 5, 6, 30 and 31 have been cancelled, and new claims 32-85 have been added. Therefore, claims 1, 4, 7-14, 22-29 and 32-85 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 4-14 and 22-31, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 10 in the amendment filed January 24, 2005.
4. The previous rejection of claims 4-14, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at pages 11-12 in the amendment filed January 24, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1, 22-28, 37-39, 45-46 and 72-73 are rejected under 35 U.S.C. 102(b) as anticipated by Malmberg *et al.* (J. Am. Coll. Cardio. 26, 57-65 (1995)).

Malmberg *et al.* teach the use of insulin-glucose infusion followed by multidose insulin treatment in diabetic patients with acute myocardial infarction for three months or longer (Table 4), where infusion of glucose and insulin was carried out in the patients according to the protocol (Table 1) to maintain the blood glucose in the target range of 7 (corresponding to 126 mg/dl) to 10.9 mmole (about 196 mg/dl). For patients in the infusion group, blood glucose decreased from 15.4 ± 4.1 to 9.6 ± 3.3 mmol/l (corresponding to 113 to 232 mg/dl), and at hospital discharge, blood glucose decreased to 8.2 ± 3.1 mmol/l (corresponding to 92 to 203 mg/dl; Table 3; claims 1, 22-28, 37-39, 45-46 and 72-73). The blood glucose level of the patient can decrease to 113 or 92 mg/dl with the treatment, and the diabetic patients with acute myocardial infarction have a high mortality rate are critically ill patients, which meet the criteria of the claims.

6. Claims 1, 22-25, 27-29, 37-39, 45-46 and 72-73 are rejected under 35 U.S.C. 102(b) as anticipated by Shangraw *et al.* (Metabolism 38, 983-989 (1989)).

Shangraw *et al.* teach insulin infusion is used in septic patients and patients with severe burn injury, where the plasma glucose levels of patients maintain between 80 to 120 mg/dl (page 985, right column; Fig. 3; claims 1, 22-25, 27-29, 37-39, 45-46 and 45-46 and 72-73). Since the claim does not identify the disease in the critically ill patient, and the septic patients and patients with severe burn injury are treated as critically ill patients, which meet the criteria of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 22-25, 27-29, 37-39, 45-46 and 72-73 are rejected under 35

U.S.C. 103(a) as being unpatentable over Case *et al.* (Crit. Cure Nurs. Q 22, 75-89

(February 2000)) in view of Gutierrez *et al.* (U. S. Patent 5,885,980).

Case *et al.* teach hyperglycemia is a frequently encountered problem when feeding critically ill patients, whether related to stress or to underlying diabetes mellitus, and subcutaneously administered regular and NPH insulin are used to achieve control; and it is suggested that insulin is administered to maintain the blood glucose concentration less than 200 mg/dl as the target range (page 86). However, Case *et al.* does not disclose the specific target range for blood glucose concentration. Gutierrez *et al.* teach the normal glucose levels are between 90 and 110 mg/dl, which is the target range for effective treatment of diabetes (column 5, lines 46-64; Example 1). At the time of invention was made, it would be obvious that one of ordinary skill in the art is motivated to use an insulin regimen to lower the blood glucose concentration in critically ill patients as taught by Case *et al.* to a target range of 90-110 mg/dl as taught by Gutierrez *et al.* (claims 1, 22-25, 27-29, 37-39, 45-46 and 72-73) because the blood glucose level of 90-110 mg/dl is a normal concentration for effective treatment of diabetes. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

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8. Claims 32-36, 40-44 and 62-71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

9. Claims 1, 22-29, 37-39, 45-46 and 72-73 are rejected; claims 32-36, 40-44 and 62-71 are objected to; and it appears claims 4, 7-14, 47-61 and 74-85 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CMK
March 17, 2005